RESPONSE

The Examiner has rejected claims 22-33 under 35 U.S.C. §112 2nd paragraph. The Examiner states that claims 22 and 23 and dependent claims thereof refer to a designation of α interferon which is termed "B/D" or "BDBB". The Examiner believes that these terms are indefinite and unclear. The Applicant earnestly solicits that the terms B/D and BDBB are established terms in the art of interferon hybrids and one of ordinary skill in the art would understand and be readily able to discern the specific types of α interferon to which the Applicants refer via the use of the terms "B/D" and "BDBB" hybrids.

To illustrate this, the Applicants invite the Examiner's attention to the Applicants disclosure in the Specification which refers to EP 0331635 (on page 1 line 12) and EP 0205404 (on page 2 lines 6 and 7). These two references were included with the Information Disclosure form PTO-1449 that was filed on February 12, 2002 by the Applicants. EP 0205404 describes the amino acid sequences of various B and D sections of hybrids of α interferon starting on the last sentence of page 4 and continuing through page 7. These examples are illustrative. To further appreciate the manner in which B/D hybrids of α interferon are characterized, one may look at figure 3 of EP0205404 which shows restriction maps of plasmid constructs of α interferon which elaborate four different types of B and D segments of the coding regions of plasmids which correspond to the B and D segments of α interferon. These B and D segments are those which are specified and referred to in the examples on page 4 through 7 of EP 0205404.

Further, EP 0331635 also categorized the B/D hybrids of α interferon by referring to the examples of EP 0205404 (see page 2 lines 40 – 45). Additional examples may be found in US 4414150 which is also referred to (in page 2 lines 40-45) of the Applicants' Specification.

Therefore, the Applicants earnestly solicit that the α interferon hybrids B/D and BDBB are definitively described by the Applicants' disclosure and would be readily understood in structure and amino acid sequence to one of ordinary skill in the art. Based on the foregoing, the Applicants respectfully request that the Examiner withdraw his rejections under 35 U.S.C. §112.

The Examiner has rejected claims 22 – 33 under 35 U.S.C. § 103 (a) as being unpatentable over Fidler, et al. (EP 0331635A2) in view of Weiner, et al (WO 91/01719). The Examiner indicates that Fidler, et al. teaches the use of an α interferon B/D or BDBB hybrid in a liposome preparation in the treatment of bladder carcinomas and as an anti-viral agent. The Examiner

further states that Fidler et al teaches the use of PC and PS that can be included to make liposomes that meet the limitations of the instant claims. The Examiner cites, from Fidler, ratios of the liposome to α interferon which are within the range of 1:300-400. The Examiner cites Weiner, et al. for the fact that the reference teaches interferons in a liposome composition that comprise a range of 1:0.5.0:0.01 to 3:3:1 of neutral:cholesterol:negatively charged phospholipids.

The Applicants disagree with the characterization of Fidler et al and Weiner et al and believe that they do not suggest to one of skill in the art that there would be a reasonable expectation of success in creating compositions of the present invention of liposomes of α interferon B/D or BDBB hybrids for injection as a treatment for viral liver disease. The Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §103 (a) based on these grounds.

Fidler does teach and claim a composition of a liposome formulation of an α interferon B/D or BDBB hybrid for injection as a treatment for bladder cancer. However, Fidler teaches and claims the use of a phosphatidyl choline and a phosphatidyl serine in a liposome composition which contains only those two phospolipids and not three components as required in the Applicants' invention. In addition, Fidler teaches and claims novel phospholipids which cause the liposome formulations to selectively attach to bladder cancer cells (see page 2 lines 60 -62). In contrast, the Applicants' invention allows a combination of one of each three components being 1) any regularly occurring neutral phospholipids, 2) cholesterol and 3) any regularly occurring negatively charged phospholipids (see page 1 lines 23 – 26) which are in correct proportions as claimed and described in the Specification.

Weiner teaches and claims a topical formulation of liposomes for which to deliver a peptide or protein to the skin (see page 11 line 7 through page 12 line 10 and claims 1 – 22). Weiner does not teach or suggest a composition which could be used for intravenous administration as compared to the Applicants present invention. Weiner's Example 2 indicates that three lipid compositions were tested - two of which had either lecithin:cholesterol:phosphatidyl or dimyristoylphosphatidyl-choline:cholesterol:phosphatidyl serine in the ratios of 2:1:0.33 and a third which had four components (the last of which the Applicants believe is outside the scope of the requirements of the present invention). The Applicants claim a specific range of three lipid components which are used to create a liposome composition having a transition temperature of 20 C to 30C. This is crucial for the use of such composition in an injectable formulation. One would not have been motivated to create an injectable composition of interferon, as in the

Applicants present invention, based on the teachings of Weiner based on a topical formulation of interferon.

Based on the foregoing the Applicants respectfully request that the rejections under 35 U.S.C. §112 and § 103 (a) be withdrawn. The Applicants believe the claims are in condition for allowance and request early notice to that effect.

If it will further prosecution of this application the Examiner is urged to contact the Applicants' attorney at the telephone number listed below.

Respectfully submitted,

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